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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,004	12/15/2003	Yi Feng Zheng	7459	2953

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LEGAL DEPARTMENT
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EXAMINER	
HAQ, SHAFIQUL	
ART UNIT	**PAPER NUMBER**
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/736,004	ZHENG ET AL.	
	Examiner	Art Unit	
	Shafiqul Haq	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,15-19,21,24,25,27,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,15-19,21,24,25,27,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-12, 14, 20, 22-23, 26, 28-29 and 32 have been cancelled.

2. Claims 13,15-19, 21, 24-25, 27 and 30-31 are pending and under active prosecution.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 13,15-19, 21, 24-25, 27 and 30-31 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Hui et al. (EP 1340981 A2) in view of Avenia et al. (US 4,041,076).

Claims recite methods, compositions and kits for detecting the presence and/or amounts of entactogens in samples.

Hui et al. disclose various competitive and noncompetitive methods/assays and a kit for detection and quantitative determination of amphetamine derivatives such as MDA, MDMA, MDEA, MDPA, BDB, MBDB etc (paragraphs [0012], [0024], [0029], [0064-0067], [0059] and [0060]) using antibody against amphetamine derivatives and label derivatives (such as fluorescent, luminescent, radioactive isotope etc.) (paragraph [0022]).

Hui's amphetamine derivatives and immunogens are similar to the compound and immunogen of the present invention and are expected to recognize different amphetamine derivatives suitable for different immunoassays. However, the linking

group or the position of linker at the amphetamine derivative is different from the present compound.

Avenia et al. disclose amphetamine immunogen, labeled tracer and antibodies (see the teaching of Avenia in above paragraph 5) and disclose competitive immunoassay method for detection of phenentylamines (e.g. norepinephrine, dopamine, epinephrine and amphetamines). The immunogen of Avenia et al. is the same as the immunogen of present application.

Since detection of amphetamine, methamphetamine and their derivatives is important in the field of ecstasy drug and once a hapten, immunogen or an antibody is available, one would obviously try to use the hapten and the immunogen in different immunoassay methods to develop a better detection assay for the drug.

Therefore, given the above fact, it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute equivalent hapten, immunogen or antibody as disclosed by Avenia et al in the method of Hui et al, with the expectation of obtaining a similarly useful immunoassay method and kit for detection of amphetamine and amphetamine derivatives.

5. Claims 13,15-19, 21, 24-25, 27 and 30-31 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Rouhani et al. (GB 2361473 A) in view of Avenia et al. (US 4,041,076).

Claims recite methods, compositions and kits for detecting the presence and/or amounts of entactogens in samples.

Rouhani et al. disclose a method for detection of ecstasy-class analogs. Rouhani discloses preparation of antibody (page 6, lines 19-24; pages 16-18) using the compound conjugated with carrier protein (see abstract) and different homogeneous and heterogeneous immunoassay methods (pages 8-9 and 34) and assay kit (page 31, lines 9-12 and claim 10) for detection and quantitation of ecstasy-class analogs in biological samples (page 22, lines19-24). Rouhani also discloses the above compound conjugated with a protein to be adapted as immunogen (page 41, example 7). Attachment to a carrier protein or a label is also inherent in the process of immunization (see claims 7 and 8) and immunoassay methods (see pages 8-9 and 34) as disclosed in this reference.

Rouhani's amphetamine and methamphetamine derivatives and immunogens are similar to the compound and immunogen of the present invention and are expected to recognize different amphetamine derivatives suitable for different immunoassays. However, the linking group or the position of linker at the amphetamine derivative is different from the present compound.

Avenia et al. disclose amphetamine immunogen, labeled tracer and antibodies (see the teaching of Avenia in above paragraph 5) and disclose competitive immunoassay method for detection of phenentylamines (e.g. norepinephrine, dopamine, epinephrine and amphetamines). The immunogen of Avenia et al. is the same as the immunogen of present application.

Sine detection of amphetamine, methamphetamine and their derivatives is important in the field of ecstasy drug and once a hapten, immunogen or an antibody

is available, one would obviously try to use the hapten and the immunogen in different immunoassay methods to develop a better detection assay for the drug.

Therefore, given the above fact, it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute equivalent hapten, immunogen or antibody as disclosed by Avenia et al in the method of Rouhani et al, with the expectation of obtaining a similarly useful immunoassay method and kit for detection of amphetamine and amphetamine derivatives.

Response to Argument

6. Applicant's arguments and amendments filed 10/31/06 have been fully considered, and are persuasive to overcome the rejections of 8/8/06 under 35 USC 102, but they are not persuasive to overcome rejections of 8/8/06 under 35 USC 103.

Applicants' argued that Avenia is concerned with conventional immunogenic carrier conjugates and there is no mention in Avenia of conjugates of labels including enzyme labels, and the haptens. This is not found convincing because Avenia et al. clearly envisaged using labeled phehenthylamine in a competitive immunoassay using antibody against phenenthylamine conjugate. Avenia et al., in lines 35-58 of column 4, states:

> "The specific antibodies of the present invention are useful as reagents for the determination of phenethylamines of formumula I. In such an assay, **known amount of labeled phenethylamine is mixed with the above antibody** and the sample containing phenethylamine is added. The amount of phenethylamines in the sample can be determined by measuring the inhibition of the binding to the specific antibody of the labeled phenethalylamine by the unknown sample. The reagents may be added in any order. ----------. Suitable labeled phenethylamines for assay purposes include radioisotopically labeled phenethylamines ----------. **One may also employ phenethylamines labeled with any other**

> **unique and detectable label ---------. Other suitable labels include chromophores, fluorophores, enzymes, red blood cells, latex particles, etc."**

Applicants' argued that the labeled derivative Avenia employs is a radioactive amphetamine analoge. While this is true, Avenia also contemplates using other label derivatives such as fluorophores and enzymes as described above. Therefore, in view of the teaching of various competitive and noncompetitive immunoassay formats as disclosed in the method of Hui et al. and Rouhani et al., use of enzyme or fluorophore labeled conjugate of Avenia is obvious to one of ordinary skill in the art.

Conclusion

7. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHAFIQUL HAQ
EXAMINER
ART UNIT 1641

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